

**MEDTRONIC Sofamor Danek
ANATOMIC PEEK™ CERVICAL FUSION SYSTEM
November 2011**

- I. **Company:** Medtronic Sofamor Danek, USA
Inc.
1800 Pyramid Place
Memphis, Tennessee 38132
(901) 396-3133
- II. **Contact:** Becky Ronner
Regulatory Affairs Specialist
Telephone: (901) 399-2757
Fax: (901) 346-9738
- III. **Proposed Proprietary Trade Name:** ANATOMIC PEEK™ CERVICAL FUSION SYSTEM
- IV. **Classification Names:** Intervertebral Body Fusion Device
Class: II
Product Code: ODP (21 CFR 888.3080)

- V. **Description:**
The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is designed for use as a cervical interbody fusion device. The device is manufactured from PEEK™ OPTIMA™ and is to be used with autogenous bone graft.

The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM consists hemi-cylindrical of cages of various widths, heights and depths. The hollow geometry of the implants allows them to be inserted between two cervical vertebral bodies packed with autogenous bone graft in cervical fusion procedures. The ANATOMIC PEEK™ device is to be used with cleared cervical supplemental fixation.

- VI. **Indications for Use:**
The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated

disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The ANATOMIC® PEEK™ device is to be used with supplemental fixation. The ANATOMIC PEEK™ CERVICAL FUSION SYSTEM is also required to be used with autogenous bone graft and is to be implanted via an open, anterior approach.

VII. Summary of the Technological Characteristics:

The purpose of this 510(k) submission is to seek clearance for a cervical interbody fusion indication for the ANATOMIC PEEK™ CERVICAL FUSION SYSTEM. The design is essentially the same fundamental technology with minor dimensional changes to the predicate VERTE-STACK Anatomic PEEK™ Spinal System.

VIII. Identification of Legally Marketed Devices:

The design features and indications for use for the subject ANATOMIC PEEK™ CERVICAL FUSION SYSTEM are substantially equivalent to predicates:

- VERTE-STACK Anatomic PEEK™ Spinal System(K070173, SE 3/14/2007)
- CORNERSTONE® PSR Cervical Interbody Fusion Device (K100214, SE 6/25/2010)
- PEEK PREVAIL™ Cervical Interbody Device (K094042, SE 6/30/2010)
- Depuy Bengal System (K081917, SE 5/22/2009)
- Small PLATEAU® (Plateau-C) (K093093, SE 10/13/2010)

IX. Discussion of Non-Clinical Testing:

The subject ANATOMIC PEEK™ CERVICAL FUSION Devices were tested in accordance ASTM F2077-03 "Test Methods for Intervertebral Body Fusion Devices", ASTM F2267-04 "Standard Test Method for Measuring Load Induced Subsidence of the Intervertebral Body Fusion Device under Static Axial Compression" and ASTM F-04.25.02.02 "Draft Static Push-out Test Method for Intervertebral Body Fusion Devices". A full list of tests conducted includes:

K112444

- Static Compression
- Static Compression Shear
- Compression Fatigue
- Compression Shear Fatigue
- Static Torsion
- Torsion Fatigue
- Static Subsidence
- Static Expulsion

The subject devices met the predetermined acceptance criteria for all tests. Test results were provided to demonstrate that the subject devices are substantially equivalent to the predicate devices.

X. Conclusion:

A risk analysis was completed and non-clinical performance testing was performed. Based on the test results and additional supporting documentation provided in this pre-market notification, we believe that the subject device demonstrates substantial equivalence to the listed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

NOV 15 2011

Medtronic Sofamor Danek, USA Inc.
% Ms. Becky Ronner
Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K112444

Trade/Device Name: ANATOMIC PEEK™ CERVICAL FUSION SYSTEM
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: August 15, 2011
Received: August 24, 2011

Dear Ms. Ronner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

f Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K112444

Device Name: ANATOMIC PEEK CERVICAL FUSION SYSTEM

Indications for Use:

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112444